



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA-HQ-OPPT-2010-0279; FRL-9326-2]

RIN 2070-AB27

Proposed Significant New Use Rules on Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing significant new use rules (SNURs) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for 17 chemical substances which were the subject of premanufacture notices (PMNs). Fifteen of these chemical substances are subject to TSCA section 5(e) consent orders issued by EPA. This action would require persons who intend to manufacture, import, or process any of these 17 chemical substances for an activity that is designated as a significant new use by this proposed rule to notify EPA at least 90 days before commencing that activity. The required notification would provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs.

DATES: Comments must be received on or before *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2010-0279, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* OPPT Document Control Office (DCO), EPA East, Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA-HQ-OPPT-2010-0279. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA-HQ-OPPT-2010-0279. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov website is an “anonymous access” system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your

comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:*

Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-9232; e-mail address:

moss.kenneth@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; e-mail address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, import, process, or use the chemical substances contained in this proposed rule. Potentially affected entities may include, but are not limited to:

- Manufacturers, importers, or processors of one or more subject chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in § 721.5. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to

the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to a final SNUR must certify their compliance with the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see § 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What Action is the Agency Taking?

These proposed SNURs would, when finalized, require persons to notify EPA at least 90 days before commencing the manufacture, import, or processing of the specific chemical substances identified in the PMNs for any activity designated by these SNURs as a significant new use. Receipt of such notices allows EPA to assess risks that may be presented by the intended uses and, if appropriate, to regulate the proposed use before it occurs. Additional rationale and background to these rules are more fully set out in the preamble to EPA's first direct final SNUR published in the **Federal Register** of April 24,

1990 (55 FR 17376). Consult that preamble for further information on the objectives, rationale, and procedures for SNURs and on the basis for significant new use designations, including provisions for developing test data.

B. What is the Agency's Authority for Taking this Action?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a “significant new use.” EPA must make this determination by rule after considering all relevant factors, including the TSCA section 5(a)(2) factors, listed in Unit III. of this document. Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) and 40 CFR part 721 requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture, import, or process the chemical substance for that use. Persons who must report are described in § 721.5.

C. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the final rule. Provisions relating to user fees appear at 40 CFR part 700.

According to § 721.1(c), persons subject to these SNURs must comply with the same notice requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA may take regulatory action under TSCA section 5(e),

5(f), 6, or 7 to control the activities for which it has received the SNUN. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in the **Federal Register** its reasons for not taking action.

III. Significant New Use Determination

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorized EPA to consider any other relevant factors.

To determine what would constitute a significant new use for the 17 chemical substances that are the subject of these proposed SNURs, EPA considered relevant information about the toxicity of the chemical substances, likely human exposures and environmental releases associated with possible uses, taking into consideration the four bulleted TSCA section 5(a)(2) factors listed in this unit.

IV. Substances Subject to this Proposed Rule

EPA is proposing to establish significant new use and recordkeeping requirements for 17 chemical substances in 40 CFR part 721, subpart E. In this unit, EPA provides the following information for each chemical substance:

- PMN number.
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service (CAS) number (if assigned for non-confidential chemical identities).
- Basis for the TSCA section 5(e) consent order or, for non-section 5(e) SNURs, the basis for the SNUR (i.e., SNURs without TSCA section 5(e) consent orders).
- Toxicity concerns.
- Tests recommended by EPA to provide sufficient information to evaluate the chemical substance (see Unit VIII. for more information).
- CFR citation assigned in the regulatory text section of this proposed rule.

This proposed rule includes 7 PMN substances whose reported chemical names include the term “carbon nanotube” or “CNT”. Because of a lack of established nomenclature for carbon nanotubes, the TSCA Inventory names for carbon nanotubes are currently in generic form, e.g., carbon nanotube (CNT), multi-walled carbon nanotube (MWCNT), double-walled carbon nanotube (DWCNT), or single-walled carbon nanotube (SWCNT). EPA uses the specific structural characteristics provided by the PMN submitter to more specifically characterize the Inventory listing for an individual CNT. All submitters of new chemical notices for CNTs have claimed those specific structural characteristics as CBI. EPA is publishing the generic chemical name along with

the PMN number to identify that a distinct chemical substance was the subject of the PMN without revealing the confidential chemical identity of the PMN substance.

Confidentiality claims preclude a more detailed description of the identity of these CNTs.

If an intended manufacturer, importer, or processor of CNTs is unsure of whether its CNTs are subject to this proposed SNUR or any other SNUR, the company can either contact EPA or obtain a written determination from EPA pursuant to the bona fide procedures at § 721.11. EPA is using the specific structural characteristics, for all CNTs submitted as new chemical substances under TSCA, to help develop standard nomenclature for placing these chemical substances on the TSCA Inventory. EPA has compiled a generic list of those structural characteristics entitled “Material Characterization of Carbon Nanotubes for Molecular Identity (MI) Determination & Nomenclature.” A copy of this list is available in the docket for these proposed SNURs under docket ID number EPA-HQ-OPPT-2010-0279. If EPA develops a more specific generic chemical name for these materials, that name will be made publicly available.

The regulatory text section of this proposed rule specifies the activities designated as significant new uses. Certain new uses, including exceeding production volume limits (i.e., limits on manufacture and importation volume) and other uses designated in this rule, may be claimed as CBI.

This proposed rule includes 15 PMN substances for which EPA determined, pursuant to TSCA section 5(e), that uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal may present an unreasonable risk of injury to human health or the environment. Accordingly, these substances are subject to “risk-based” consent orders under TSCA section 5(e)(1)(A)(ii)(I). Those consent orders require

protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The so-called “5(e) SNURs” on these PMN substances are proposed pursuant to § 721.160, and are based on and consistent with the provisions in the underlying consent orders. The 5(e) SNURs designate as a “significant new use” the absence of the protective measures required in the corresponding consent orders.

Where EPA has determined that the PMN substance may present an unreasonable risk of injury to human health via inhalation exposure, the underlying TSCA section 5(e) consent order usually requires, among other things, that potentially exposed employees wear specified respirators unless actual measurements of the workplace air show that airborne concentrations of the PMN substance are below a New Chemical Exposure Limit (NCEL) that is established by EPA to provide adequate protection to human health. In addition to the actual NCEL concentration, the comprehensive NCELs provisions in TSCA section 5(e) consent orders, which are modeled after Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PELs) provisions, include requirements addressing performance criteria for sampling and analytical methods, periodic monitoring, respiratory protection, and recordkeeping. However, no comparable NCEL provisions exist in 40 CFR part 721, subpart B, for SNURs. Therefore, for these cases, the individual SNURs in 40 CFR part 721, subpart E, will state that persons subject to the SNUR who wish to pursue NCELs as an alternative to the § 721.63 respirator requirements may request to do so under § 721.30. EPA expects that persons whose § 721.30 requests to use the NCELs approach for SNURs are approved by EPA will be required to comply with NCELs provisions that are comparable to those contained in the corresponding TSCA section 5(e) consent order for the same chemical substance.

This proposed rule also includes SNURs on 2 PMN substances that are not subject to a consent order under TSCA section 5(e). In these cases, for a variety of reasons, EPA did not find that the use scenario described in the PMN met the criteria set forth under TSCA section 5(e). However, EPA does believe that certain changes from the use scenario described in these PMNs could result in increased exposures, and therefore should be designated a significant new use. These so-called “non-5(e) SNURs” are being proposed pursuant to § 721.170. EPA has determined that every activity designated as a “significant new use” in all non-5(e) SNURs issued under § 721.170 satisfies the two requirements stipulated in § 721.170(c)(2), i.e., these significant new use activities, “(i) are different from those described in the premanufacture notice for the substance, including any amendments, deletions, and additions of activities to the premanufacture notice, and (ii) may be accompanied by changes in exposure or release levels that are significant in relation to the health or environmental concerns identified” for the PMN substance.

PMN Number P-04-244

Chemical name: Ethane, 2-bromo-1, 1-difluoro-.

CAS number: 359-07-9.

Effective date of the TSCA section 5(e) consent order: February 16, 2010.

Basis for the TSCA section 5(e) consent order: The PMN states that the substance will be used as a chemical intermediate for an herbicide. The order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that this substance may present an unreasonable risk of injury to human health. To protect against this risk, the consent order: (1) Requires use of personal protective equipment including impervious

gloves and a National Institute for Occupational Safety and Health (NIOSH)-certified supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a tight-fitting full facepiece with an assigned protection factor (APF) of at least 75, or compliance with a NCEL of 0.5 mg/m^3 as an 8-hour time-weighted average; (2) requires establishment of a hazard communication program; (3) prohibits use of the PMN substance other than as a chemical intermediate for an herbicide; and (4) requires corresponding recordkeeping. The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

Toxicity concern: Based on test data on analogous structurally similar alkyl halides, EPA identified health concerns for systemic toxicity, developmental toxicity, reproductive toxicity, and cancer in workers exposed to the PMN substance by the inhalation route.

Recommended testing: EPA has determined that a carcinogenicity test (OPPTS Test Guideline 870.4200) in rats by the inhalation route would help characterize the human health effects of the PMN substance. The PMN submitter has agreed not to exceed a particular production volume limit without performing this test.

CFR citation: 40 CFR 721.10265.

PMN Numbers P-08-733 and P-08-734

Chemical names: Multi-walled carbon nanotubes (generic) (P-08-733 and P-08-734).

CAS numbers: Not available.

Effective date of the TSCA section 5(e) consent order: July 26, 2010.

Basis for the TSCA section 5(e) consent order: The PMNs state that the generic (non-confidential) uses of the substances will be as: Reinforcement for composites, conductive additive for composites, and conductive additive for batteries. The order was issued under

TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that these substances may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the consent order: (1) Requires use of personal protective equipment including gloves and chemical protective clothing, and a NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N-100, P-100, or R-100 filter with an APF of at least 50; (2) prohibits the domestic manufacture of the PMN substances; (3) restricts use of the PMN substances to those uses specified in the consent order; prohibits the release of the PMN substances into the waters of the United States; and (4) requires corresponding recordkeeping. The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

Toxicity concern: Based on test data for analogous chemicals, including other carbon nanotubes, there are concerns for pulmonary toxicity, fibrosis, carcinogenicity, mutagenicity, and immunotoxicity of the PMN substances. Based on test data on respirable, poorly soluble particulates, EPA has concerns for lung effects. There are also data suggesting that pulmonary deposition of some nanoscale materials, including carbon nanotubes in the agglomerated form, may induce cardiovascular toxicity when these nanoscale materials are inhaled. The major health concerns are for potential pulmonary toxicity, fibrosis, and cancer to workers exposed via inhalation. Sublethal effects have been noted for some carbon nanoscale substances in fish at levels as low as 100 parts per billion (ppb). Further, studies need to be conducted before EPA can determine a concentration of concern. Such studies must measure actual concentrations of carbon nanotubes and control for the effects of contaminants, solvents, and physical factors such as blockage of gills or intestines.

Recommended testing: EPA has determined that the following tests would help characterize possible effects of the substances. The PMN submitter has agreed not to exceed a specified production limit without performing these tests on one of the PMN substances: A 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465 or Organisation for Economic Co-operation and Development (OECD) Test Guideline 413) with a post-exposure observation period of up to 3 months, bronchoalveolar lavage fluid (BALF) analysis, a determination of cardiovascular toxicity (clinically-based blood/plasma protein analyses), and histopathology of the heart and certain material characterization data.

CFR citation: 40 CFR 721.10266.

PMN Numbers P-09-54, P-09-55, P-09-56, and P-09-57

Chemical names: (P-09-54) [5,6]Fullerene-C60-Ih; (P-09-55) [5,6]Fullerene-C70-D5h(6); (P-09-56) [5,6]Fullerene-C84-D2; and (P-09-57) [5,6]Fullerene-C84-D2d.

CAS numbers: (P-09-54) 99685-96-8; (P-09-55) 115383-22-7; (P-09-56) 145809-19-4; and (P-09-57) 145809-20-7.

Effective date of the TSCA section 5(e) consent order: August 16, 2010.

Basis for the TSCA section 5(e) consent order: The PMN states that uses of the substances will be as: An intermediate compound for use in producing downstream products that will in turn be used in organic electronic devices and an additive to improve mechanical properties or conductivity; a compound used to improve the mechanical properties of rubbers, plastics, and lubricants; and a compound for use as an additive to increase the conductivity of materials. The order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that these substances may present an

unreasonable risk of injury to human health. To protect against this risk, the consent order: (1) Requires use of personal protective equipment including gloves and protective clothing impervious to the chemical substances and a NIOSH-certified full-face respirator with N-100 cartridges; (2) restricts use of the PMN substances to those uses specified in the consent order; (3) prohibits release of the PMN substances into the waters of the United States; and (4) requires corresponding recordkeeping. The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

Toxicity concern: Based on test data on poorly soluble particulates, including some carbon-based nano-sized chemicals, and test data correlating lung irritation to particle size, EPA has concerns for lung effects from inhalation exposure.

Recommended testing: EPA has determined that the following tests would help characterize possible effects of the substances. The PMN submitter has agreed not to exceed a particular production limit without performing these tests on all of the PMN substances: Dry particle size distribution by count for each PMN substance in a form which has the highest content of particles smaller than 10 microns as manufactured, processed, or used in the workplace at sites controlled by the PMN submitter (the method shall be scanning transmission electron microscopy, using a dry particle counting method, with a resolution of less than 1 nanometer and with no counting after dispersion in a solution and evaporating solvent) and dustiness (EN 15051 method).

EPA has determined that the results of the following tests would help characterize the human health effects of the PMN substance. The order does not require the submission of the following information at any specified time or production volume: 90-day inhalation toxicity (OPPTS Test Guideline 870.3465 or OECD Test Guideline 413);

dispersion and solubility in fresh water without the use of dispersants or solvents (Refs. 1 and 2). However, the order's restrictions on manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance will remain in effect until the order is modified or revoked by EPA based on submission of that or other relevant information.

CFR citations: 40 CFR 721.10267 (P-09-54); 40 CFR 721.10268 (P-09-55); 40 CFR 721.10269 (P-09-56); and 40 CFR 721.10270 (P-09-57).

PMN Numbers P-09-142, P-09-143, P-09-144, and P-09-416

Chemical names: (P-09-142 and Chemical A in P-09-416) 3'H-cyclopropa[1,9][5,6]fullerene-C60-Ih-3'-butanoic acid, 3'-phenyl-, methyl ester; (P-09-143 and Chemical B in P-09-416) 3'H-cyclopropa[8,25][5,6]fullerene-C70-D5h(6)-3'-butanoic acid, 3'-phenyl-, methyl ester; and (P-09-144 and Chemical C in P-09-416) 3'H-cyclopropa[7,22][5,6]fullerene-C70-D5h(6)-3'-butanoic acid, 3'-phenyl-, methyl ester.

CAS numbers: (P-09-142 and Chemical A in P-09-416) 160848-22-6; (P-09-143 and Chemical B in P-09-416) 609771-63-3; and (P-09-144 and Chemical C in P-09-416) 1051371-21-1.

Effective date of the TSCA section 5(e) consent orders: (P-09-142, P-09-143, and P-09-144) November 1, 2010 and (P-09-416) October 28, 2010.

Basis for the TSCA section 5(e) consent orders: The PMNs state that the uses of the substances will be: As a compound used in fabrication and/or operation of electronic devices that enables or improves the conductivity, efficiency, voltage, or other characteristics of the device, and a compound that improves the mechanical properties of lubricants and plastics (P-09-142, P-09-143, and P-09-144), and as acceptor molecules in a polymer coating in an encapsulated organic photovoltaic electronic device (P-09-416).

The orders were issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that these substances may present an unreasonable risk of injury to human health. To protect against these risks, the consent orders: (1) Require the use of personal protective equipment including impervious gloves and chemical protective clothing and use of a NIOSH-certified air-purifying tight-fitting full-face respirator equipped with N-100 cartridges; (2) restrict use of the PMN substances to those uses specified in their respective consent orders; (3) prohibit release of the PMN substances into the waters of the United States; and (4) require corresponding recordkeeping. The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

Toxicity concern: Based on test data on poorly soluble particulates, including some carbon-based nano-sized chemicals, and test data correlating lung irritation to particle size, EPA has concerns for lung effects from inhalation exposure.

Recommended testing: EPA has determined that the following tests would help characterize the human health effects of the PMN substances. The consent orders each contain two production limits. The PMN submitters have agreed not to exceed their first production limits without performing a 90-day inhalation toxicity study (OPPTS Test Guideline 870.3465 or OECD Test Guideline 413) in rats with a post exposure observation period of up to 3 months, including a BALF analysis, a determination of cardiovascular toxicity (clinically-based blood/plasma protein analyses), and histopathology of the heart and certain material characterization data on the test material which can be any one of these PMN substances. The PMN submitters have also agreed not to exceed the second production limits without providing certain physical-chemical properties on each of the PMN substances.

The consent order for P-09-416 does not require the submission of the following information at any specified time or production volume: Dispersion and solubility in fresh water without the use of dispersants or solvents (Refs. 1 and 2) and daphnid chronic toxicity test (OPPTS Test Guideline 850.1300). However, the order's restrictions on manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance will remain in effect until the order is modified or revoked by EPA based on submission of that or other relevant information.

CFR citations: 40 CFR 721.10271 (P-09-142 and Chemical A in P-09-416); 40 CFR 721.10272 (P-09-143 and Chemical B in P-09-416); and 40 CFR 721.10273 (P-09-144 and Chemical C in P-09-416).

PMN Number P-09-188

Chemical name: Multi-walled carbon nanotubes (generic) (P-09-188).

CAS number: Not available.

Effective date of the TSCA section 5(e) consent order: December 14, 2010.

Basis for the TSCA section 5(e) consent order: The PMN states that the generic (non-confidential) use of the substance will be as an electric conductive filler to replace conventional material such as carbon black or carbon fiber in matrices such as polymer resin for conductive applications. The order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that this substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the consent order: (1) Requires use of personal protective equipment including gloves and chemical protective clothing impervious to the PMN substance, and a NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N-100, P-

100, or R-100 filter with an APF of at least 50; (2) prohibits domestic manufacture in the United States; (3) restricts use of the PMN substance to those uses specified in the consent order; (4) prohibits the manufacture, processing, or use of the PMN substance for commercial or consumer products, or in a consumer product; prohibits release of the PMN substance into the waters of the United States; and (5) requires corresponding recordkeeping. The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

Toxicity concern: Based on test data for analogous chemicals including other carbon nanotubes there are concerns for pulmonary toxicity, fibrosis, carcinogenicity, mutagenicity, and immunotoxicity of the PMN substance. Based on test data on respirable, poorly soluble particulates, EPA has concerns for lung effects. There are also data suggesting that pulmonary deposition of some nanoscale materials, including carbon nanotubes in the agglomerated form, may induce cardiovascular toxicity when these nanoscale materials are inhaled. The major health concerns are for potential pulmonary toxicity, fibrosis, and cancer to workers exposed via inhalation. Sublethal effects have been noted for some carbon nanoscale substances in fish at levels as low as 100 ppb. Further studies need to be conducted before EPA can determine a concentration of concern. Such studies must measure actual concentrations of carbon nanotubes and control for the effects of contaminants, solvents, and physical factors such as blockage of gills or intestines.

Recommended testing: EPA has determined that the following tests would help characterize possible effects of the PMN substance. The PMN submitter has agreed not to exceed two production volume limits specified in the order without performing these

tests: A 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465 or OECD Test Guideline 413) with a post-exposure observation period of up to 3 months, a BALF analysis, determination of cardiovascular toxicity, heart histopathology, data on pulmonary deposition, and certain material characterization and physical-chemical properties on the test material(s).

The order does not require the submission at any specified time or production volume of the following exposure data on representative forms of the PMN substance: Release of the PMN substance after landfill disposal (EPA Method 1320), release of the PMN substance during burning (American Society for Testing and Materials International (ASTM) E1354-09), release of the PMN substance after exposure to sunlight (ASTM D2565-99 (2008)), and release of the PMN substance during shipping and use. However, the order's restrictions on manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance will remain in effect until the order is modified or revoked by EPA based on submission of that or other relevant information. The company may propose alternative methods, guidelines, or representative sets subject to EPA's approval.

CFR citation: 40 CFR 721.10274.

PMN Number P-09-417

Chemical name: Multi-walled carbon nanotubes (generic) (P-09-417).

CAS number: Not available.

Effective date of the TSCA section 5(e) consent order: March 23, 2010.

Basis for the TSCA section 5(e) consent order: The PMN states that the use of the substance will be as a plastics additive to improve electrical, thermal, and/or mechanical

properties. The order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that this substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the consent order: (1) Requires use of personal protective equipment including gloves and protective clothing impervious to the chemical substance and NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N-100, P-100, or R-100 filter with an APF of 50; (2) prohibits the domestic manufacture of the PMN substance; (3) restricts use of the PMN substance to the uses specified in the consent order; (4) prohibits use of the PMN substance in commercial or consumer products; (5) prohibits release of the PMN substance into the waters of the United States during processing and use activities; and (6) requires corresponding recordkeeping. The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

Toxicity concern: Based on test data for analogous chemicals including other carbon nanotubes there are concerns for pulmonary toxicity, fibrosis, carcinogenicity, mutagenicity, and immunotoxicity of the PMN substance. Based on test data on the PMN substance and respirable, poorly soluble particulates, EPA has concerns for lung effects. There are also data suggesting that pulmonary deposition of some nanoscale materials, including carbon nanotubes in the agglomerated form, may induce cardiovascular toxicity when these nanoscale materials are inhaled. The major health concerns are for potential pulmonary toxicity, fibrosis, and cancer to workers exposed via inhalation. Sublethal effects have been noted for some carbon nanoscale substances in fish at levels as low as 100 ppb. Further studies need to be conducted before EPA can determine a concentration of concern. Such studies must measure actual concentrations of carbon nanotubes and

control for the effects of contaminants, solvents, and physical factors such as blockage of gills or intestines.

Recommended testing: EPA has determined that the following test would help characterize the possible effects of the PMN substance. The PMN submitter has agreed not to exceed the production limit without providing certain physical/chemical properties test data. The order does not require the submission of the following information at any specified time or production volume: The results of a combined chronic toxicity/carcinogenicity testing of respirable fibrous particles test (OPPTS Test Guideline 870.8355). However, the order's restrictions on manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance will remain in effect until the order is modified or revoked by EPA based on submission of that or other relevant information.

CFR citation: 40 CFR 721.10275.

PMN Numbers P-10-39 and P-10-40

Chemical names: Multi-walled carbon nanotubes (generic) (P-10-39) and single-walled and multi-walled carbon nanotubes (generic) (P-10-40).

CAS numbers: (P-10-39) Not available and (P-10-40) not available.

Effective date of the TSCA section 5(e) consent order: August 30, 2010.

Basis for the TSCA section 5(e) consent order: The PMN states that the generic (non-confidential) use of the substances will be as composite structures for defense, electronic, and aerospace applications. The order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding that these substances may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the

consent order: (1) Requires use of personal protective equipment including gloves and protective clothing impervious to the chemical substances, and a NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N-100, P-100, or R-100 filter with an APF of at least 50; (2) restricts use of the PMN substances to the uses specified in the consent order; (3) prohibits manufacture, processing, or use of the PMN substance for commercial or consumer products; (4) prohibits release of the PMN substances into the waters of the United States; and (5) requires corresponding recordkeeping. The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

Toxicity concern: Based on test data for analogous chemicals including other carbon nanotubes there are concerns for pulmonary toxicity, fibrosis, carcinogenicity, mutagenicity, and immunotoxicity of the PMN substances. Based on test data on respirable, poorly soluble particulates, EPA has concerns for lung effects. There are also data suggesting that pulmonary deposition of some nanoscale materials, including carbon nanotubes in the agglomerated form, may induce cardiovascular toxicity when these nanoscale materials are inhaled. The major health concerns are for potential pulmonary toxicity, fibrosis, and cancer to workers exposed via inhalation. Sublethal effects have been noted for some carbon nanoscale substances in fish at levels as low as 100 ppb. Further studies need to be conducted before EPA can determine a concentration of concern. Such studies must measure actual concentrations of carbon nanotubes and control for the effects of contaminants, solvents, and physical factors such as blockage of gills or intestines.

Recommended testing: EPA has determined that the following tests would help characterize the possible effects of the PMN substances. The consent order contains three production limits. The PMN submitter has agreed not to exceed the first production limit without submitting certain material characterization data on both substances. The PMN submitter has agreed not to exceed the second production limit without performing workplace exposure monitoring and characterization testing (including byproducts) as well as quantification and characterization of substances that may be released during exposures typical during the use phase. The PMN submitter has also agreed not to exceed the third production limit without performing a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465 or OECD Test Guideline 413) with a post-exposure observation period of up to 3 months, a BALF analysis, determination of cardiovascular toxicity, heart histopathology, data on pulmonary deposition, and certain material characterization and physical-chemical properties on either or both of the substances that workers may be exposed to.

CFR citations: 40 CFR 721.10276 (P-10-39) and 40 CFR 721.10277 (P-10-40).

PMN Number P-10-224

Chemical name: 4,4'-Bipyridinium, 1-(phosphonoalkyl)-1'-substituted-, salt with anion (1:2) (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a constituent in ink formulation. Based on test data on a salt of the anion of the PMN substance and analogous respirable poorly soluble particulates, EPA identified concerns for toxicity concerns to the liver and lung and neurotoxicity to workers exposed

to the PMN substance. For the uses described in the PMN, significant worker exposure is unlikely, as dermal and inhalation exposure will be minimal due to adequate personal protective equipment and no domestic manufacture. Therefore, EPA has not determined that the proposed manufacturing method, processing method, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the PMN substance: (1) Without the use of impervious gloves where there is potential for dermal exposure, (2) without the use of a NIOSH-certified respirator with an APF of at least 10 where there is potential inhalation exposure, (3) involving domestic manufacture, (4) other than as described in the PMN, (5) where the annual manufacture and importation volume exceeds 1,000 kilograms, or (6) in the form of a powder or a solid may cause serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465 or OECD Test Guideline 413) would help characterize the human health effects of the PMN substance.

CFR citation: 40 CFR 721.10278.

PMN Number P-10-246

Chemical name: Multi-walled carbon nanotubes (generic) (P-10-246).

CAS number: Not available.

Effective date of the TSCA section 5(e) consent order: April 4, 2011.

Basis for the TSCA section 5(e) consent order: The PMN states that the use of the substance will be as a conductivity additive to resins, rubber, and battery electrodes. The order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a

finding that this substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the order: (1) Requires use of personal protective equipment including gloves and protective clothing impervious to the chemical substance, and at minimum, a NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N-100, P-100, or R-100 cartridges or power air purifying particulate respirator with an APF of at least 50; (2) prohibits the domestic manufacture of the PMN substance; (3) restricts use of the PMN substance to the uses specified in the consent order; (4) prohibits release of the PMN substance into the waters of the United States during processing and use activities; and (5) requires corresponding recordkeeping. The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

Toxicity concern: Based on test data for analogous chemicals including other carbon nanotubes there are concerns for pulmonary toxicity, fibrosis, carcinogenicity, mutagenicity, and immunotoxicity of the PMN substances. Based on test data on respirable, poorly soluble particulates, EPA has concerns for lung effects. There are also data suggesting that pulmonary deposition of some nanoscale materials, including carbon nanotubes in the agglomerated form, may induce cardiovascular toxicity when these nanoscale materials are inhaled. The major health concerns are for potential pulmonary toxicity, fibrosis, and cancer to workers exposed via inhalation. Sublethal effects have been noted for some carbon nanoscale substances in fish at levels as low as 100 ppb. Further studies need to be conducted before EPA can determine a concentration of concern. Such studies must measure actual concentrations of carbon nanotubes and

control for the effects of contaminants, solvents, and physical factors such as blockage of gills or intestines.

Recommended testing: EPA has determined that the results of the following tests would help characterize possible effects of the PMN substance. The PMN submitter has agreed not to exceed a specified production time limit before performing these tests on the PMN substance: A 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465 or OECD Test Guideline 413) in rats with a post exposure observation period of up to 3 months, including a BALF analysis, a determination of cardiovascular toxicity (clinically-based blood/plasma protein analyses), and histopathology of the heart and certain material characterization data.

CFR citation: 40 CFR 721.10279.

PMN Number P-10-476

Chemical name: Benzene, ethenyl-, polymer with 1,3-butadiene.

CAS number: 1195978-93-8.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a polymer additive. Based on analogous high molecular weight polymers, EPA identified concerns for potential lung overload from exposure to the PMN substance via inhalation. Specifically, EPA predicts potential toxicity to consumers and the general population from inhalation of respirable particles of 10 microns or less of the PMN substance where the average number molecular weight is greater than 10,000 daltons. Further, based on the physical/chemical properties of the PMN substance, EPA has concluded, if the PMN substance were manufactured where the average number molecular weight is less than 1,000 daltons, the PMN substance may be considered

persistent, bio-accumulative, and toxic (PBT), as described in the New Chemical Program's PBT category (64 FR 60194; November 4, 1999) (FRL-6097-7). EPA estimates, if the PMN substance were manufactured where the average number molecular weight is less than 1,000 daltons, that the PMN substance will persist in the environment more than six months and estimates a bioaccumulation factor of greater than or equal to 1,000. For the manufacturing method, processing method, and use described in the PMN, significant inhalation exposures are unlikely, and the PMN is not considered to be a PBT. Accordingly, EPA has not determined that the proposed manufacturing method, processing method, or use of the substance as described in the PMN notice may present an unreasonable risk. EPA has determined, however, that any manufacturing method, processing method, or use of the PMN substance where greater than 5 percent of the particles are in the respirable range of 10 microns or less and the average number molecular weight is greater than 10,000 daltons may cause serious health effects. EPA has also determined that any manufacturing method, processing method, or use of the PMN substance where the average number molecular weight is less than 1,000 daltons may cause significant adverse environmental effects and may be characterized as a potential PBT substance. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(3)(ii), (b)(4)(ii), and (b)(4)(iii).

Recommended testing: EPA has determined that the results of the following testing would help characterize the possible human health effects and potential PBT attributes of the PMN substance: a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465 or OECD Test Guideline 413) with a 60-day holding period (for the PMN substance where greater than 5 percent is in the respirable range of 10 microns or less and the average

number molecular weight is greater than 10,000 daltons) and the tiered testing described in the New Chemicals Program's PBT Category (64 FR 60194; November 4, 1999) (FRL-6097-7) (for the PMN substance where the average number molecular weight is less than 1,000 daltons). Test reports should include protocols approved by EPA, certificate of analysis for the test substance, raw data, and results.

CFR citation: 40 CFR 721.10280.

V. Rationale and Objectives of the Proposed Rule

A. Rationale

During review of the PMNs submitted for the chemical substances that are subject to these proposed SNURs, EPA concluded that for 15 of the 17 chemical substances, regulation was warranted under TSCA section 5(e), pending the development of information sufficient to make reasoned evaluations of the health or environmental effects of the chemical substances. The basis for such findings is outlined in Unit IV. Based on these findings, TSCA section 5(e) consent orders requiring the use of appropriate exposure controls were negotiated with the PMN submitters. The proposed SNUR provisions for these chemical substances are consistent with the provisions of the TSCA section 5(e) consent orders. These SNURs are being proposed pursuant to § 721.160.

In the other 2 cases, where the uses were not regulated under a TSCA section 5(e) consent order, EPA determined that one or more of the criteria of concern established at § 721.170 were met, as discussed in Unit IV.

B. Objectives

EPA is proposing these SNURs for specific chemical substances which have undergone premanufacture review because the Agency wants to achieve the following objectives with regard to the significant new uses designated in this proposed rule:

- EPA would receive notice of any person's intent to manufacture, import, or process a listed chemical substance for the described significant new use before that activity begins.
- EPA would have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing, importing, or processing a listed chemical substance for the described significant new use.
- EPA would be able to regulate prospective manufacturers, importers, or processors of a listed chemical substance before the described significant new use of that chemical substance occurs, provided that regulation is warranted pursuant to TSCA sections 5(e), 5(f), 6, or 7.
- EPA would ensure that all manufacturers, importers, and processors of the same chemical substance that is subject to a TSCA section 5(e) consent order are subject to similar requirements.

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Inventory. Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the Internet at

<http://www.epa.gov/opptintr/existingchemicals/pubs/tscainventory/index.html>.

VI. Notice and Comment Procedures

EPA is issuing these SNURs by notice and comment procedure, as described in § 721.170(d)(4). In accordance with § 721.170(d)(4)(ii)(A), persons are being given the

opportunity to submit comments on or before [*insert date 30 days after date of publication in the **Federal Register***] on whether EPA should establish notification requirements.

VII. Applicability of Proposed Rule to Uses Occurring Before Effective Date of the Final Rule

To establish a significant “new” use, EPA must determine that the use is not ongoing. The chemical substances subject to this proposed rule have undergone premanufacture review. TSCA section 5(e) consent orders have been issued for 15 chemical substances and the PMN submitters are prohibited by the TSCA section 5(e) consent orders from undertaking activities which EPA is designating as significant new uses. EPA is soliciting comments on whether any of the uses proposed as significant new uses are ongoing.

As discussed in the **Federal Register** of April 24, 1990, EPA has decided that the intent of TSCA section 5(a)(1)(B) is best served by designating a use as a significant new use as of the date of publication of this proposed rule rather than as of the effective date of the final rule. If uses begun after publication of the proposed rule were considered ongoing rather than new, it would be difficult for EPA to establish SNUR notice requirements because a person could defeat the SNUR by initiating the significant new use before the rule became final, and then argue that the use was ongoing before the effective date of the final rule. Thus, persons who begin commercial manufacture, import, or processing of the chemical substances that would be regulated through these proposed SNURs will have to cease any such activity before the effective date of the rule if and when finalized. To resume their activities, these persons would have to comply with all

applicable SNUR notice requirements and wait until the notice review period, including all extensions, expires.

EPA has promulgated provisions to allow persons to comply with these proposed SNURs before the effective date. If a person were to meet the conditions of advance compliance under § 721.45(h), the person would be considered exempt from the requirements of the SNUR.

VIII. Test Data and Other Information

EPA recognizes that TSCA section 5 does not require developing any particular test data before submission of a SNUN. There are two exceptions:

1. Development of test data is required where the chemical substance subject to the SNUR is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)(1)).
2. Development of test data may also be necessary where the chemical substance has been listed under TSCA section 5(b)(4) (see TSCA section 5(b)(2)).

In the absence of a TSCA section 4 test rule or a TSCA section 5(b)(4) listing covering the chemical substance, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (see § 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing.

In the TSCA section 5(e) consent orders for 15 of the chemical substances regulated under this proposed rule, EPA has established restrictions in view of the lack of data on the potential health and environmental risks that may be posed by the significant new uses or increased exposure to the chemical substances. These restrictions will not be removed until EPA determines that the unrestricted use will not present an unreasonable

risk of injury or result in significant or substantial exposure or environmental release.

This determination is usually made based on the results of the required or recommended toxicity tests.

In cases where EPA issued a TSCA section 5(e) consent order that requires or recommends certain testing, Unit IV. lists tests required or recommended in each of the section 5(e) consent orders underlying the proposed 5(e) SNURs, and lists tests recommended for the substances subject to the proposed non-5(e) SNURs. Descriptions of tests are provided for informational purposes. EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. To access the OPPTS Test Guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select “Test Methods and Guidelines.” The Organisation for Economic Co-operation and Development (OECD) test guidelines are available from the OECD Bookshop at <http://www.oecdbookshop.org> or SourceOECD at <http://www.sourceoecd.org>. The American Society for Testing and Materials International (ASTM) standards are available at <http://www.astm.org/Standard/index.shtml>. To access the European standard, EN 15051 method, issued by The European Committee for Standardization (CEN), please go to <http://www.cen.eu/cen/products>. To access EPA Method 1320, please go to <http://www.epa.gov/osw/hazard/testmethods/sw846/pdfs/1320.pdf>.

When physical/chemical properties of test material and/or material characterization tests are recommended for nanoscale substances that are the subject of this proposed rule, you should take into consideration the characterizations identified in the Guidance Manual for the Testing of Manufactured Nanomaterials: OECD’s

Sponsorship Programme, which is available at

[http://www.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono\(2009\)20/rev&doclanguage=en](http://www.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono(2009)20/rev&doclanguage=en).

The recommended testing specified in Unit IV. of this document may not be the only means of addressing the potential risks of the chemical substance. However, submitting a SNUN without any test data may increase the likelihood that EPA will take action under TSCA section 5(e), particularly if satisfactory test results have not been obtained from a prior PMN or SNUN submitter. EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

- Human exposure and environmental release that may result from the significant new use of the chemical substances.
- Potential benefits of the chemical substances.
- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

IX. SNUN Submissions

According to § 721.1(c), persons submitting a SNUN must comply with the same notice requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in § 720.50. SNUNs must be submitted to EPA on EPA Form No. 7710-25 in accordance

with the procedures set forth in § 721.25 and § 720.40. Forms and information are available on-line at <http://www.epa.gov/opptintr/newchems>.

X. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers, importers, and processors of the chemical substances subject to this proposed rule. EPA's complete Economic Analysis is available in the docket under docket ID number EPA-HQ-OPPT-2010-0279.

XI. References

The following is a listing of the documents that have been placed in the proposed rule phase of the docket under docket ID number EPA-HQ-OPPT-2010-0279, which is available for inspection as specified under **ADDRESSES**.

1. Cheng, X., Kan, A.T., and Tomson, M.B. Napthalene Adsorption and Desorption from Aqueous C₆₀ Fullerene. *Journal of Chemical & Engineering Data*. 2004, 49 (3), 675-683.
2. Brant, J., Lecoanet, H., Hotze, M., and Wiesner, M. Comparison of Electrokinetic properties of Colloidal Fullerenes (n-C₆₀) Formed Using Two Procedures. *Environmental Science & Technology* 2005, 39 (17), 6343-6351.

XII. Statutory and Executive Order Reviews

A. Executive Order 12866

This proposed rule would establish SNURs for several new chemical substances that were the subject of PMNs, and, in some cases, TSCA section 5(e) consent orders. The Office of Management and Budget (OMB) has exempted these types of actions from

review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993).

B. Paperwork Reduction Act

According to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, an Agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable. EPA would amend the table in 40 CFR part 9 to list the OMB approval number for the information collection requirements contained in these proposed SNURs, if the SNURs are subsequently issued as final rules. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of PRA and OMB's implementing regulations at 5 CFR part 1320. This Information Collection Request (ICR) was previously subject to public notice and comment prior to OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend it is unnecessary. As a result, EPA finds that there is "good cause" under section 553(b)(3)(B) of the Administrative Procedure Act, 5 U.S.C. 553(b)(3)(B), to amend this table without further notice and comment.

The information collection requirements related to this action have already been approved by OMB pursuant to PRA under OMB control number 2070-0012 (EPA ICR No. 574). This action would not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to

average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Collection Strategies Division, Office of Environmental Information (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that promulgation of these SNURs would not have a significant adverse economic impact on a substantial number of small entities. The rationale supporting this conclusion is discussed in this unit. The requirement to submit a SNUN applies to any person (including small or large entities) who intends to engage in any activity described in the proposed rule as a “significant new use.” Because these uses are “new,” based on all information currently available to EPA, it appears that no small or large entities presently engage in such activities. A SNUR requires that any person who intends to engage in such activity in the future must first notify EPA by submitting a SNUN. Although some small entities may decide to pursue a significant new use in the future, EPA cannot presently determine how many, if any, there may be. However, EPA’s experience to date is that, in response to the promulgation of SNURs covering

over 1,000 chemicals, the Agency receives only a handful of notices per year. For example, the number of SNUNs was four in Federal fiscal year (FY) 2005, eight in FY 2006, six in FY 2007, eight in FY 2008, and seven in FY 2009. During this 5-year period, three small entities submitted a SNUN. In addition, the estimated reporting cost for submission of a SNUN (see Unit X.) is minimal regardless of the size of the firm. Therefore, the potential economic impacts of complying with these SNURs would not be expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published in the **Federal Register** of June 2, 1997 (62 FR 29684) (FRL-5597-1), the Agency presented its general determination that final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

D. Unfunded Mandates Reform Act

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government would be impacted by this proposed rule. As such, EPA has determined that this proposed rule would not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of sections 202, 203, 204, or 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

E. Executive Order 13132

This action would not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999).

F. Executive Order 13175

This proposed rule would not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This proposed rule would not significantly nor uniquely affect the communities of Indian Tribal governments, nor would it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000), do not apply to this proposed rule.

G. Executive Order 13045

This action is not subject to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

H. Executive Order 13211

This proposed rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply,

distribution, or use and because this action is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

In addition, since this action does not involve any technical standards, section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note), does not apply to this action.

J. Executive Order 12898

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: December 19, 2011.

Wendy C. Hamnett,

Director, Office of Pollution Prevention and Toxics.

Therefore, it is proposed that 40 CFR part 721 be amended as follows:

PART 721--[AMENDED]

1. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

2. Add § 721.10265 to subpart E to read as follows:

§ 721.10265 Ethane, 2-bromo-1, 1-difluoro-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as ethane, 2-bromo-1, 1-difluoro- (PMN P-04-244; CAS No. 359-07-9) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance after it has been completely reacted (cured).

- (2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(3), (a)(4), (a)(6)(v), (a)(6)(vi), (b) (concentration set at 0.1 percent), and (c). The following National Institute for Occupational Safety and Health (NIOSH)-certified respirator with an assigned protection factor (APF) of at least 75 meets the minimum requirements for § 721.63(a)(4): NIOSH-certified supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a tight-fitting full facepiece.

(A) As an alternative to the respiratory requirements listed in paragraph (a)(2)(i), a manufacturer, importer, or processor may choose to follow the new chemical exposure limit (NCEL) provisions listed in the TSCA section 5(e) consent order for this substance. The NCEL is 0.5 mg/m³ as an 8-hour time-weighted average. Persons who wish to pursue

NCEs as an alternative to the § 721.63 respirator requirements may request to do so under § 721.30. Persons whose § 721.30 requests to use the NCEs approach are approved by EPA will receive NCEs provisions comparable to those contained in the corresponding section 5(e) consent order.

(B) [Reserved]

(ii) *Hazard communication program*. Requirements as specified in § 721.72 (a), (b), (c), (d), (e) (concentration set at 0.1 percent), (f), (g)(1)(iv), (g)(1)(vi), (g)(1)(vii), (g)(1)(ix), (g)(2)(ii), (g)(2)(iii), (g)(2)(iv) (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 0.5 mg/m³), and (g)(5).

(iii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80 (k) (chemical intermediate for a herbicide), and (q).

(b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), (e), (f), (g), (h), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section*. The provisions of § 721.1725(b)(1) apply to this section.

3. Add § 721.10266 to subpart E to read as follows:

§ 721.10266 Multi-walled carbon nanotubes (generic) (P-08-733 and P-08-734).

(a) *Chemical substances and significant new uses subject to reporting.* (1) The chemical substances identified generically as multi-walled carbon nanotubes (PMNs P-08-733 and P-08-734) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substances after they have been completely reacted (cured); embedded or incorporated into a polymer matrix that has been reacted (cured); or embedded, encapsulated or incorporated by the polymer binder into a permanent solid matrix (does not include slurries) that is not intended to undergo further processing, except for mechanical processing.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(2)(ii), (a)(3), (a)(4), (a)(6)(i), (a)(6)(ii), and (c). The following National Institute for Occupational Safety and Health (NIOSH)-certified respirator with an assigned protection factor (APF) of at least 50 meets the minimum requirements for § 721.63(a)(4): NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N-100, P-100, or R-100 filter.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (f), (k), and (q).

(iii) *Release to water.* Requirements as specified in § 721.90 (a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), (e), (i), and (k) are applicable to manufacturers, importers, and processors of these substances.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this significant new use rule.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to this section.

4. Add § 721.10267 to subpart E to read as follows:

§ 721.10267 [5,6]Fullerene-C60-Ih.

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance identified as [5,6]fullerene-C60-Ih (PMN P-09-54; CAS No. 99685-96-8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance after it has been completely reacted (cured); embedded or incorporated into a polymer matrix that itself has been reacted (cured); or embedded in a permanent solid polymer form that is not intended to undergo further processing except for mechanical processing.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(2)(ii), (a)(3), (a)(4), (a)(6)(i), (a)(6)(ii), and (c). The following National Institute for Occupational Safety and Health (NIOSH)-certified respirator meets the minimum requirements for § 721.63(a)(4): NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N-100, P-100, or R-100 filter.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) (an intermediate compound for use in producing downstream products that will in turn be used in organic electronic devices and an additive to improve mechanical properties or conductivity; a compound used to improve the mechanical properties of rubbers, plastics, and lubricants; or a compound for use as an additive to increase the conductivity of materials).

(iii) *Release to water.* Requirements as specified in § 721.90 (a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), (e), (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this significant new use rule.

5. Add § 721.10268 to subpart E to read as follows:

§ 721.10268 [5,6]Fullerene-C70-D5h(6).

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance identified as [5,6]fullerene-C70-D5h(6) (PMN P-09-55; CAS No. 115383-22-7) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance after it has been completely reacted (cured); embedded or incorporated into a polymer matrix that itself has been reacted (cured); or

embedded in a permanent solid polymer form that is not intended to undergo further processing except for mechanical processing.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(2)(ii), (a)(3), (a)(4), (a)(6)(i), (a)(6)(ii), and (c). The following National Institute for Occupational Safety and Health (NIOSH)-certified respirator with an assigned protection factor (APF) of at least 50 meets the minimum requirements for § 721.63(a)(4): NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N-100, P-100, or R-100 filter.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) (an intermediate compound for use in producing downstream products that will in turn be used in organic electronic devices and an additive to improve mechanical properties or conductivity; a compound used to improve the mechanical properties of rubbers, plastics, and lubricants; or a compound for use as an additive to increase the conductivity of materials).

(iii) *Release to water.* Requirements as specified in § 721.90 (a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), (e), (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this significant new use rule.

6. Add § 721.10269 to subpart E to read as follows:

§ 721.10269 [5,6]Fullerene-C84-D2.

(a) Chemical *substance and significant new uses subject to reporting.* (1) The chemical substance identified as [5,6]fullerene-C84-D2 (PMN P-09-56; CAS No. 145809-19-4) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance after it has been completely reacted (cured); embedded or incorporated into a polymer matrix that itself has been reacted (cured); or embedded in a permanent solid polymer form that is not intended to undergo further processing except for mechanical processing.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(2)(ii), (a)(3), (a)(4), (a)(6)(i), (a)(6)(ii), and (c). The following National Institute for Occupational Safety and Health (NIOSH)-certified respirator meets the minimum requirements for § 721.63(a)(4): NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N-100, P-100, or R-100 filter.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) (an intermediate compound for use in producing downstream products that will in turn be used in organic electronic devices and an additive to improve mechanical properties or conductivity; a compound used to improve the mechanical properties of

rubbers, plastics, and lubricants; or a compound for use as an additive to increase the conductivity of materials).

(iii) *Release to water*. Requirements as specified in § 721.90 (a)(1), (b)(1), and (c)(1).

(b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), (e), (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this significant new use rule.

7. Add § 721.10270 to subpart E to read as follows:

§ 721.10270 [5,6]Fullerene-C84-D2d.

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified as [5,6]fullerene-C84-D2d (PMN P-09-57; CAS No. 145809-20-7) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance after it has been completely reacted (cured); embedded or incorporated into a polymer matrix that itself has been reacted (cured); or embedded in a permanent solid polymer form that is not intended to undergo further processing except for mechanical processing.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(2)(ii), (a)(3), (a)(4), (a)(6)(i), (a)(6)(ii), and (c). The following National Institute for Occupational Safety and Health (NIOSH)-certified respirator meets the minimum requirements for § 721.63(a)(4): NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 cartridges.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) (an intermediate compound for use in producing downstream products that will in turn be used in organic electronic devices and an additive to improve mechanical properties or conductivity; a compound used to improve the mechanical properties of rubbers, plastics, and lubricants; or a compound for use as an additive to increase the conductivity of materials).

(iii) *Release to water.* Requirements as specified in § 721.90 (a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), (e), (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this significant new use rule.

8. Add § 721.10271 to subpart E to read as follows:

§ 721.10271 3'H-cyclopropa[1,9][5,6]fullerene-C60-1h-3'-butanoic acid, 3'-phenyl-, methyl ester.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 3'H-cyclopropa[1,9][5,6]fullerene-C60-Ih-3'-butanoic acid, 3'-phenyl-, methyl ester, (PMNs P-09-142 and Chemical A in P-09-416; CAS No. 160848-22-6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substances after they have been completely reacted (cured); embedded or incorporated into a polymer matrix that itself has been reacted (cured); or embedded in a permanent solid polymer form that is not intended to undergo further processing, except for mechanical processing.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(2)(ii), (a)(3), (a)(4), (a)(6)(i), (a)(6)(ii), and (c). The following National Institute for Occupational Safety and Health (NIOSH)-certified respirator meets the minimum requirements for § 721.63(a)(4): NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 cartridges.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (k) (use as a compound used in fabrication and/or operation of electronic devices that enables or improves the conductivity, efficiency, voltage, or other characteristics of the device and a compound that improves the mechanical properties of lubricants and plastics; or use as an acceptor molecule in a polymer coating in an encapsulated organic photovoltaic electronic device) and (q).

(iii) *Release to water.* Requirements as specified in § 721.90 (a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), (e), (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this significant new use rule.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to this section.

9. Add § 721.10272 to subpart E to read as follows:

§ 721.10272 3'H-cyclopropa[8,25][5,6]fullerene-C70-D5h(6)-3'-butanoic acid, 3'-phenyl-, methyl ester.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances identified as 3'H-cyclopropa[8,25][5,6]fullerene-C70-D5h(6)-3'-butanoic acid, 3'-phenyl-, methyl ester (PMNs P-09-143 and Chemical B in P-09-416; CAS No. 609771-63-3) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substances after they have been completely reacted (cured); embedded or incorporated into a polymer matrix that itself has been reacted (cured); or embedded in a permanent solid polymer form that is not intended to undergo further processing, except for mechanical processing.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(2)(ii), (a)(3), (a)(4), (a)(6)(i), (a)(6)(ii), and (c). The following National Institute for Occupational Safety and Health (NIOSH)-certified respirator meets the minimum requirements for § 721.63(a)(4): NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 cartridges.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (k) (use as a compound used in fabrication and/or operation of electronic devices that enables or improves the conductivity, efficiency, voltage or other characteristics of the device and a compound that improves the mechanical properties of lubricants and plastics; or use as an acceptor molecule in a polymer coating in an encapsulated organic photovoltaic electronic device) and (q).

(iii) *Release to water.* Requirements as specified in § 721.90 (a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), (e), (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this significant new use rule.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to this section.

10. Add § 721.10273 to subpart E to read as follows:

§ 721.10273 3'H-cyclopropa[7,22][5,6]fullerene-C70-D5h(6)-3'-butanoic acid, 3'-phenyl-, methyl ester.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances identified as 3'H-cyclopropa[7,22][5,6]fullerene-C70-D5h(6)-3'-butanoic acid, 3'-phenyl-, methyl ester (P-09-144 and Chemical C in P-09-416, CAS No. 1051371-21-1) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substances after they have been completely reacted (cured); embedded or incorporated into a polymer matrix that itself has been reacted (cured); or embedded in a permanent solid polymer form that is not intended to undergo further processing, except for mechanical processing.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(2)(ii), (a)(3), (a)(4), (a)(6)(i), (a)(6)(ii), and (c). The following National Institute for Occupational Safety and Health (NIOSH)-certified respirator meets the minimum requirements for § 721.63(a)(4): NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 cartridges.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (k) (use as a compound used in fabrication and/or operation of electronic devices that enables or improves the conductivity, efficiency, voltage or other characteristics of the device and a compound that improves the mechanical properties of

lubricants and plastics; or use as an acceptor molecule in a polymer coating in an encapsulated organic photovoltaic electronic device) and (q).

(iii) *Release to water.* Requirements as specified in § 721.90 (a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), (e), (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this significant new use rule.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to this section.

11. Add § 721.10274 to subpart E to read as follows:

§ 721.10274 Multi-walled carbon nanotubes (generic) (P-09-188).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as multi-walled carbon nanotubes (PMN P-09-188) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance after it has been completely reacted (cured); embedded or incorporated into a polymer matrix that itself has been reacted (cured); or embedded in a permanent solid polymer form with a concentration of the PMN substance equal to or

below 30 percent that is not intended to undergo further processing except for mechanical processing.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(2)(ii), (a)(3), (a)(4), and (c). The following National Institute for Occupational Safety and Health (NIOSH)-certified respirator meets the minimum requirements for § 721.63(a)(4): NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N-100, P-100, or R-100 filter.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (f), (k), (m), (o), and (q).

(iii) *Release to water.* Requirements as specified in § 721.90 (a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), (e), (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this significant new use rule.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to this section.

12. Add § 721.10275 to subpart E to read as follows:

§ 721.10275 Multi-walled carbon nanotubes (generic) (P-09-417).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as multi-walled carbon nanotubes (PMN P-09-417) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance after it has been completely reacted (cured); embedded or incorporated into a polymer matrix that itself has been reacted (cured); or embedded in a permanent solid polymer form that is not intended to undergo further processing, except for mechanical processing.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(2)(ii), (a)(3), (a)(4), (a)(6)(i), (a)(6)(ii), and (c). The following National Institute for Occupational Safety and Health (NIOSH)-certified respirator with an assigned protection factor (APF) of at least 50 meets the minimum requirements for § 721.63(a)(4): NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N-100, P-100, or R-100 filter.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (f), (k) (plastics additive to improve electrical, thermal, and/or mechanical properties), (m), and (o).

(iii) *Release to water.* Requirements as specified in § 721.90 (b)(1) and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), (e), (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this significant new use rule.

13. Add § 721.10276 to subpart E to read as follows:

§ 721.10276 Multi-walled carbon nanotubes (generic) (P-10-39).

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as multi-walled carbon nanotubes (PMN P-10-39) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance after it has been completely reacted (cured); embedded or incorporated into a polymer matrix that itself has been reacted (cured); or embedded in a permanent solid polymer, metal, glass, or ceramic form that is not intended to undergo further processing except for mechanical processing.

(2) The significant new uses are:

(i) *Protection in the workplace*. Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(2)(ii), (a)(3), (a)(4), and (c). The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an approved protection factor (APF) of at least 50 meets the minimum requirements for § 721.63(a)(4): NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N-100, P-100, or R-100 filter.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (k), (m), (o), and (p) (120,000 kilograms of the aggregate of this chemical substance and the substance in § 721.10277 for P-10-40).

(iii) *Release to water.* Requirements as specified in § 721.90 (a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), (e), (i), and (k) are applicable to manufacturers, importers, and processors of these substances.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this significant new use rule.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to this section.

14. Add § 721.10277 to subpart E to read as follows:

§ 721.10277 Single-walled and multi-walled carbon nanotubes (generic) (P-10-40).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as single-walled and multi-walled carbon nanotubes (PMN P-10-40) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance after it has been completely reacted (cured); embedded or incorporated into a polymer matrix that itself has been reacted (cured); or

embedded in a permanent solid polymer, metal, glass, or ceramic form that is not intended to undergo further processing except for mechanical processing.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(2)(ii), (a)(3), (a)(4), and (c). The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 50 meet the minimum requirements for § 721.63(a)(4): NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N-100, P-100, or R-100 filter.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (k), (m), (o), and (p) (120,000 kilograms of the aggregate of this chemical substance and the substance in § 721.10276 for P-10-39).

(iii) *Release to water.* Requirements as specified in § 721.90 (a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), (e), (i), and (k) are applicable to manufacturers, importers, and processors of these substances.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this significant new use rule.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to this section.

15. Add § 721.10278 to subpart E to read as follows:

§ 721.10278 4,4'-Bipyridinium, 1-(phosphonoalkyl)-1'-substituted-, salt with anion (1:2) (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as 4,4'-bipyridinium, 1-(phosphonoalkyl)-1'-substituted-, salt with anion (1:2) (PMN P-10-224) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(3) (applicable to gloves only), (a)(4), (a)(6), (b) (concentration set at 1.0 percent), and (c). The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of 10-25 meet the minimum requirements for § 721.63(a)(4):

(A) NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(B) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(C) NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate air (HEPA) filters;

(D) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters; or

(E) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (f), (j), (s) (1,000 kilograms), (v)(1), and (v)(2).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), (e), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to this section.

16. Add § 721.10279 to subpart E to read as follows:

§ 721.10279 Multi-walled carbon nanotubes (generic) (P-10-246).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as multi-walled carbon nanotubes (PMN P-10-246) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance after it has been completely reacted (cured); embedded or incorporated into a polymer matrix that itself has been reacted (cured); or embedded in a

permanent solid polymer form that is not intended to undergo further processing, except for mechanical processing.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(2)(ii), (a)(3), (a)(4), (a)(6)(i), (a)(6)(ii), and (c). The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 50 meet the minimum requirements for § 721.63(a)(4):

(A) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(B) NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate air (HEPA) filters; or

(C) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (f), (k) (conductivity additive to resins, rubber, and to battery electrodes), and (q).

(iii) *Release to water.* Requirements as specified in § 721.90 (b)(1) and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), (e), (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this significant new use rule.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to this section.

17. Add § 721.10280 to subpart E to read as follows:

§ 721.10280 Benzene, ethenyl-, polymer with 1,3-butadiene.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as benzene, ethenyl-, polymer with 1,3-butadiene (PMN P-10-476; CAS No. 1195978-93-8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (j) (manufacture by the method where the average number molecular weight is in the range of 1,000 to 10,000 daltons or where less than 5 percent of the particles are in the respirable range of 10 microns or less and the average number molecular weight is greater than or equal to 10,000 daltons).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

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